GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1484
ANSWERED ON:24.07.2002
PERMISSION OF NEW DRUGS
BHIM PRASAD DAHAL

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of applications pending for permission of new drugs at present;

(b) the reasons for their pending; and

(c) the time by which these applications are likely to be cleared?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a)to(c): The evaluation of new drug applications is a complex and continuous process as per Schedule-Y under Drugs and Cosmetics Rules and varies according to the nature of molecule/drug. Therefore, depending upon the nature of the application, it may take on an average more than 5 years for approval of investigational New Drug (i.e. a drug molecule not tested on human being anywhere in the world) about 1-3 years for the first time approval of the drug already approved elsewhere but requiring confirmatory clinical trial and about 2-3 months for subsequent applications for already approved drugs. This is, however, subject to submission of all required data as per provisions of Schedule-Y of Drug and Cosmetics Rules.

Since the issue of Gazette Notification vide GSR No.900 (E) dated 12th December, 2001 till 30th June, 2002, this office has received 528 applications alogwith requisite fees for approval of various categories of New Drugs which includes Investigational New Drugs (IND), Unapproved New Drugs, Generic version of New Drugs, New Dosage Form and Modified Release of New Drugs etc. Out of this following 70 cases has been approved based on the satisfactory clinical trial/Bio-equivalence study report, Laboratory test report etc:

1. Cases of new drug application (NDA) - 9

2. Cases of Bulk Drug - 4

3. Cases of subsequent New Drug Application (Generic) (SNDA) - 29

4. Cases of modified drug release formulation - 1

5. Cases of Fixed Dose combination - 10
6. Cases of new Dosage form - 16

7 Cases of new indication - 1

Remaining cases are under various stages of evaluation such as under clinical trial/and or Bio-equivalence study, or in consultation with the subject expert or at laboratory testing stage etc. As soon as the satisfactory reports are received from the laboratory/applicant the approval will be accorded.